For submission to the Head of Laboratory

(CITY), January xxth 2017

Reference: RC-16-0082

URGENT – FIELD SAFETY NOTICE

LOTS RECALL (SEE LIST ON THE APPENDIX): DISPOSABLE STA®-CUVETTES (REF. 38669) FOR HAEMOSTASIS ANALYSERS STA-R®, STA R MAX®, STA COMPACT®, STA COMPACT MAX®

Dear Madam, Dear Sir,

According to our records you have ordered and received in your laboratory one or several lots of STA®-Cuvettes (reference 38669) used on our haemostasis analysers STA-R®, STA R Max®, STA Compact® or STA Compact Max®.

Please find hereafter details of an issue which has been detected regarding some lots of STA®-Cuvettes.

✓ **Identification and description of the defect:**

Following a customer complaint, Diagnostica Stago investigated a report of erroneous APTT results when using several lots of STA®-Cuvettes (listed in the appendix).

Internal investigations have shown that this is a random issue with a low occurrence. For example, with a standard customer test profile, the average rate of outliers is 0.4 %. All erroneous results observed during investigations have shortened clotting times, with a mean relative deviation of 30 % on APTT tests.

The affected clotting parameters are the following: APTT, Factor VIII, Factor IX, Protein S and Protein C clotting assays. The issue is not related to the type and the lot of reagent and has been reproduced both with Quality Control as well as patient plasmas.

The chromogenic, immunoturbidimetric and clotting tests other than those listed above are not affected.

✓ **Actions:**

If you have in your laboratory, any of the lots of STA®-Cuvettes among those listed in the appendix, Diagnostica Stago is asking you to:

- Identify and quarantine the concerned STA®-Cuvettes lot(s). The quarantined lots will be collected by Stago at an agreed time.
- Use other lots of STA®-Cuvettes in your stock until the affected lots can be replaced.
- Contact Stago as soon as possible in order to obtain without delay a lot exchange.

As patient results are interpreted in a global clinical context in association with other biological tests we leave at your discretion the decision to review previous patient results on a case by case basis.

Please can you complete the coupon attached acknowledging receipt of this letter. The return of this coupon will initiate the replacement process for the affected lots.

The Competent Administrative Authority of the country of origin (France) has been informed.
Your Competent Administrative Authority has also been informed regarding this issue.

For additional information, please contact your Stago affiliate.

Please accept our apologies for this inconvenience. We thank you in advance for your support.

Yours sincerely,